

FF6



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): COLE et al.  
SERIAL NO.: 10/752,937  
FILED: January 7, 2004  
FOR: METHODS FOR DETECTING PREGNANCY  
GROUP ART UNIT: 1645  
EXAMINER:

---

Mail Stop DD  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 223313-1450

### INFORMATION DISCLOSURE STATEMENT

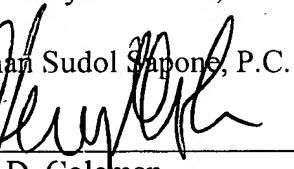
SIR:

Pursuant to the Duty to Disclose under 37 C.F.R. §1.56(a), applicant encloses herewith a copy of Form PTO-1449 listing patent and other documents relevant to the background of the invention described and claimed in the above-identified application. These patents/references were also cited in United States Patent No. 6,627,457 B2. For the convenience of the Examiner, copies of the listed foreign patent and non-patent documents are enclosed.

Applicant respectfully requests that the Examiner consider the enclosed references in determining the patentability of the claimed invention. Applicant also requests that the Examiner return a copy of enclosed Form PTO-1449 with initials or other marks indicating that the references have been so considered. If any fee is due, please charge/credit deposit account no. 04-0838.

Respectfully submitted,

Coleman Sudol Sapone, P.C.

By:   
Henry D. Coleman  
Reg. No. 32,559  
714 Colorado Avenue  
Bridgeport, Connecticut 06605-1601  
(203)366-3560

Dated: June 24, 2004



### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: "Mail Stop DD, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on June 24, 2004.

Harold Hull  
Harold Hull

**INFORMATION DISCLOSURE  
CITATION IN AN APPLICATION**

Att'y Ref: N12-002 Serial No: 10/752,937

Applicant: COLE et al.

Filing Date: Jan. 7, 2004 Art Unit: 1645

**United States Patent Documents**

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date
	4,946,958	08/1990	Campbell et al.			
	5,356,817	10/1994	Cole			
	5,506,150	04/1996	Canick et al.			
	5,660,990	08/1997	Rao et al.			
	6,127,186	10/2000	Pandian			
	6,339,143	01/2002	Krichevsky et al.			
	6,352,862	03/2002	Davis et al.			
	6,429,018	08/2002	Cole et al.			
	6,500,627	12/2002	O'Connor et al.			

**Foreign Patent Documents**

Examiner Initial	Publication Number	Publication Date	Country	Class	Subclass	Translation	
						Yes	No
	98/10282	03/1998	WIPO				
	99/41584	08/1999	WIPO				
	99/56132	11/1999	WIPO				
	00/42428	07/2000	WIPO				

Examiner:

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered; Include a copy of this form with next communication to the applicant.



	00/70094	11/2000	WIPO			
--	----------	---------	------	--	--	--

Examiner Initial	Other Documents (by Title, Author Date, Pertinent Pages, Etc.)
	Cole LA et al., "Utility of Commonly Used Commercial Human Chorionic Gonadotropin Immunoassays in the Diagnosis and Management of Trophoblastic Diseases" <i>Clinical Chemistry</i> 47 (2000) 305-315.
	Bahado-Singh R et al., "A High-sensitivity alternative to 'routine' genetic amniocentesis: multiple urinary analytes, nuchal thickness, and age." <i>Am J Obstet Gynecol</i> 180(1 Pt 1) (1999) 169-173.
	Cole LA et al., "Urinary screening tests for fetal Down Syndrome: I. Fresh beta-core fragment" <i>Prenat Diagn.</i> 19 (1999) 340-350.
	Bahado-Singh RO et al., "New triple screen test for Down Syndrome: combined urine analytes and serum AFP." <i>J Matern Fetal Med.</i> 7 (1998) 111-114.
	Kellner LH et al., "Levels of urinary beta-core fragment, total oestriol, and the ratio of the two in second-trimester screening for Down Syndrome." <i>Prenat Diagn.</i> 17 (1997) 1135-1141.
	Cole LA et al., "Combining beta-core fragment and total oestriol measurements to test for Down Syndrome..." <i>Prenat Diagn.</i> 17 (1997) 1125-1133.
	Cuckle HS et al., "Urinary multiple marker screening for Down's Syndrome." <i>Prenat Diagn.</i> 15 (1995) 745-751.
	Bahado-Singh RO et al., "Comparison of urinary hyperglycosylated human chorionic gonadotropin concentration with the serum triple screen for Down Syndrome detection in high-risk pregnancies." <i>Am J Obstet Gynecol.</i> 183 (2000) 1114-1118.
	Cole LA et al., "Urinary screening tests for fetal Down Syndrome: II. Hyperglycosylated hCG." <i>Prenat Diagn.</i> 19 (1999) 351-359.
	Cole LA et al., "Hyperglycosylated hCG, a potential alternative to hCT in Down Syndrome screening." <i>Prenat Diagn.</i> 18 (1998) 926-933.
	Hsu JJ et al., "Urine free beta-hcg and total estriol for Down Syndrome screening during the second trimester in an Asian population." <i>Obstet Gynecol</i> 94 (1999) 107-111.

Examiner:	Date Considered:
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered; Include a copy of this form with next communication to the applicant.	

	Spencer K et al., "First-trimester urine free beta hCG, beta core, and total oestriol in pregnancies affected by Down Syndrome: implications for first-trimester screening with nuchal translucency and serum free beta hCG." <i>Prenat Diagn</i> 17 (1997) 525-538.
	Isozaki T et al., "Screening for Down Syndrome pregnancy using beta-core fragment: prospective study." <i>Prenat Diagn</i> 17 (1997) 407-413.
	Spencer K et al., "Urine free beta hCG and beta core in pregnancies affected by Down's Syndrome." <i>Prenat Diagn</i> 16 (1996) 605-613.
	Krichevsky A et al., "The development of panel of monoclonal antibodies to human luteinizing hormone and its application to immunological mapping and two-site assays." <i>Endocrine</i> 2 (1994) 551-520.
	O'Conner JF et al., "Differential Urinary Gonadotrophin Profiles in Early Pregnancy and Early Pregnancy Loss." <i>Prenat Diagn</i> 18 (1998) 1232-1240.
	Unknown "Serum Hyperglycosylated hCG: a Potential Screening test for Fetal Down Syndrome." <i>Prenat. Diagn.</i> 19 (1999) 488-490.
	Cole LA et al., "Hyperglycosylated Human Chorionic Gonadotropin (Invasive Trophoblast Antigen) Immunoassay: A New Basis for Gestational Down Syndrome Screening." <i>Clinical Chemistry</i> 45 (1999) 2109-2119.
	Abushoufa RA et al., "The development of a sialic acid specific lectin-immunoassay for the measurement of chorionic gonadotrophin glycoforms in serum and its application in normal and Down's Syndrome pregnancies." <i>Clinical Endocrinology</i> 52 (2000) 499-508.
	Birken S. et al., "Development and Characterization of Antibodies to a Nicked and Hyperglycosylated Form of hCG from a choriocarcinoma Patient." <i>Endocrine</i> 10 (1999) 137-144.
	Krichevsky A. et al., "Development, Characterization, and Application of Monoclonal Antibodies to the Native and Synthetic beta COOH-Terminal Portion of Human Chorionic Gonadotropin (hCG) that Distinguishes between the Native and Desialylated Forms of hCG" <i>Endocrinology</i> 134 (1994) 1139-1145.
	Krichevsky A et al., "Development and Characterization of a New, Highly Specific Antibody to the Human Chorionic Gonadotropin-beta Fragment." <i>Endocrinology</i> 128 (1991) 1255-1264.

Examiner:	Date Considered:
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered; Include a copy of this form with next communication to the applicant.	